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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kilian Heitz

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EXAMINER

LLOYD, EMILY M

ART UNIT

PAPER NUMBER

3736

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,072	HEITZ, KILIAN	
	Examiner	Art Unit	
	EMILY M. LLOYD	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008 and 16 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,24,25 and 27-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,24,25 and 27-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20080630</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to Applicant's 30 June 2008 and 16 January 2009 amendments. The Examiner acknowledges Applicant's substitute abstract and specification; the substitute drawing sheet for Figure 2; and the amendments to claims 22, 24, 25 and 27-42, as well as the cancellation of claims 23 and 26 and the addition of claims 43 and 44. Currently, claims 22, 24, 25 and 27-44 are pending.

Information Disclosure Statement

2. The information disclosure statement filed 30 June 2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The Examiner notes that the foreign patent document was not received and per the 30 June 2008 EFS Acknowledgement Receipt, does not appear to have been submitted.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 25, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. The current claims disclose that the data is weighted by type. However, the specification does not disclose the details of how the data is weighted by type that produces the order and percentages of weighted data claimed.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 22, 24, 25, 27, 29 and 31-44 rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 4465077 (Schneider) as modified by United States Patent 5572370 (Cho).

Regarding claim 22, Schneider discloses a device for family planning or contraception (fertility computer 40 Figure 1), comprising: a means for determining basal temperature (temperature probe 64 Figure 1), a means for input of the first day of the cycle (period entry switch 52 Figure 1), a means for input of the property of a

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biological fluid (mucus entry switch 50 Figure 1; also optional vaginal probe 108 Figure 2), a device for processing the data made available by the means (microprocessor 9 Figure 2), a memory device for storing at least some of the data made available (RAM (random access memory) storage 13 Figure 2), and a display device (fertility status (FS) LED 56 Figure 1), whereby the device for processing the data is designed such that a conclusion regarding a woman's fertility on any given day is determined as a function of at least some of the data made available by each means (Column 17 line 18 – Column 23 line 46) and this conclusion can be displayed via the display device (fertility status (FS) LED 56 Figure 1, Column 22 lines 23-41), and the data are weighted differently in determining the conclusion regarding the woman's fertility (Schneider Column 17 line 18 – Column 23 line 46).

Schneider discloses the claimed invention except for inputting the property of saliva. Cho teaches the use of the property of saliva for family planning or contraception (apparatus for determining the period of maximum fertility in women, Figures 1 and 9; also Column 5 lines 9-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the measurement of the property of saliva as taught by Cho in the invention of Schneider to provide the predictable result of providing the a probe “which help[s] detect ovulation by change in biochemical properties” (Schneider Column 26 lines 24-25) as suggested by Schneider and to provide a more convenient property of a biological fluid (the saliva testing of Cho is more convenient than the vaginal mucus testing/reporting of Schneider).

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Regarding claim 24, Schneider as modified by Cho teach the device according to claim 22, wherein the weighting of the data can be varied as a function of the stored data formerly made available (Schneider Column 18 line 64 – Column 19 line 28; also Column 20 lines 48-52).

Regarding claim 25, Schneider as modified by Cho teach the device according to claim 22, wherein the conclusion regarding the woman's fertility depends on the data made available by the means for determining the basal temperature to a greater extent than on the data made available by the means for input of the first day of the woman's cycle (Schneider basal temperature is looked at more in terms of averages and comparisons than that of the first day of the woman's cycle, Column 17 line 18 – Column 23 line 46), and the data made available by the means for input of the first day of the woman's cycle in turn has a greater influence on the conclusion regarding her fertility than does the data made available by the means for input of the properties of the saliva (Schneider uses the property of a biological fluid after the basal temperature and first day of a woman's cycle, Column 19 lines 52-59; as modified by Cho this would use the properties of the saliva instead of cervical mucus).

Regarding claim 27, Schneider as modified by Cho teach the device according to claim 22, wherein the device is equipped for processing data, such that the conclusion regarding a woman's fertility differentiates between possible fertile and infertile days and that the possible fertile and infertile days are displayed visually in different ways (Schneider fertility status (FS) LED 56 Figure 1 blinks frequently for fertile days and does not blink on infertile days, Column 22 lines 23-41).

Regarding claim 29, Schneider as modified by Cho teach the device according to claim 27, wherein transition days are also provided in the conclusion regarding the woman's fertility; these are days when no distinction is made between possible fertile days and possible infertile days, and the transition days are displayed differently visually than the possible fertile days and infertile days (Schneider fertility status (FS) LED 56 Figure 1 blinks less frequently on transition days, Column 22 lines 23-41).

Regarding claim 31, Schneider as modified by Cho teach the device according to claim 27, wherein by a means for recognizing an increase in temperature (Schneider microprocessor 9 Figure 2) from the data made available by the means for determining the basal temperature (Schneider temperature probe 64 Figure 1), whereby in determining the conclusion regarding the woman's fertility, a distinction is made between a first phase of the cycle at the beginning of the cycle and a second phase of the cycle after the rise in temperature is detected (Schneider Column 23 lines 17-28).

Regarding claim 32, Schneider as modified by Cho teach the device according to claim 31, wherein up to the end of the second cycle registered by the device, the number of possible fertile days is preselected in the conclusion regarding the woman's fertility in the second phase of the cycle (Schneider Column 16 lines 57-68; for a woman with 40 day cycles (see Schneider Column 16 lines 14-15), a 3 month/90 day period would be about 2 cycles).

Regarding claim 33, Schneider as modified by Cho teach the device according to claim 32, wherein after the first point in time, the number of possible fertile days is determined as a function of an analysis of stored data in the conclusion regarding the

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woman's fertility in the second phase of the cycle (Schneider Column 16 lines 65-68 and Column 17 line 18 – Column 23 line 46).

Regarding claim 34, Schneider as modified by Cho teach the device according to claim 33, wherein an indicator for the regularity of the duration of the cycle and/or the course of the cycle is derived from the stored data (Schneider regularity of the duration of the cycle by CL and C(1)-C(12), see table under Column 4), and the number of possible infertile days is determined as a function of this indicator (Schneider use of CL in Section G (Compute Fertility Status) Figure 3j is one example of this; see also Column 17 line 18 – Column 23 line 46) or the number of cycles registered by the device (Schneider Column 18 line 64 – Column 19 line 26) is determined in the conclusion regarding the woman's fertility in the second phase of the cycle.

Regarding claim 35, Schneider as modified by Cho teach the device according to claim 31, wherein the number of possible fertile days is determined and/or influenced as a function of the data made available by the means for input of the properties of the saliva in the conclusion regarding fertility in the second phase of the cycle (Cho Column 5 lines 9-25).

Regarding claim 36, Schneider as modified by Cho teach the device according to claim 31, wherein up to the end of the fifth cycle registered by the device, the number of possible infertile days is preselected in the conclusion regarding the woman's fertility in the first phase of the cycle (Schneider Column 16 lines 57-68; for a woman with 20 or less day cycles (see Schneider Column 16 lines 14-15), a 3 month/90 day period would be about 5 cycles (18 day cycles would result in exactly 5 cycles in 3 months/90 days)).

Regarding claim 37, Schneider as modified by Cho teach the device according to claim 36, wherein after the second point in time, the number of possible infertile days is determined as a function of an analysis of stored data in the conclusion regarding the woman's fertility in the first phase of the cycle (Schneider Column 16 lines 65-68 and Column 17 line 18 – Column 23 line 46).

Regarding claim 38, Schneider as modified by Cho teach the device according to claim 37, wherein a quality factor is derived from the stored data (Schneider DF differential value, table above Columns 5 and 6), and after the second point in time, in the conclusion regarding the woman's fertility in the first phase of the cycle, the number of possible infertile days is determined as a function of the quality factor (Schneider use of DF in Section G (Compute Fertility Status) Figure 3j, see also Column 17 line 18 – Column 23 line 46) or the number of periods registered by the device is determined as a function of some data from the means for input of the first day of the cycle.

Regarding claim 39, Schneider as modified by Cho teach the device according to claim 22, wherein a time measuring device (Schneider programmable timer 11 Figure 2) and an interactive device (Schneider space 5 Figure 1 and Column 6 lines 52-53) for instructing a user to input data after a predetermined period of time has elapsed (Schneider Column 25 lines 62-64).

Regarding claim 40, Schneider as modified by Cho teach the device according to claim 39, wherein the interactive device is designed so that an input of the properties of the saliva is instructed 5-10 times per cycle (Schneider teaches prompting for the collection of data (see Column 25 lines 62-64), Cho teaches that the saliva indicates

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fertility for approximately 5 to 7 days (Column 5 lines 25-28)). It would have been obvious to instruct the input of the properties of saliva 5-10 times per cycle in the invention of Schneider as modified by Cho to allow for additional data to confirm transition and fertile days with the testing dates indicated by the other parameters disclosed by Schneider.

Regarding claim 41, Schneider as modified by Cho teach the device according to claim 22, wherein fluctuations in temperature that are not due to the cycle but instead are caused by a cold or a migraine are recognized (Schneider Column 12 lines 50-58 and 18-22) and discarded when determining the possible fertile and/or infertile days (Schneider Column 12 lines 58-60).

Regarding claim 42, Schneider as modified by Cho teach the device according to claim 22, wherein a cycle and in particular the duration and/or the course of the cycle are recognized (Schneider duration of the cycle by CL and C(1)-C(12), see table under Column 4).

Regarding claims 43 and 44, Schneider as modified by Cho teach the device according to claim 22, with the ranking of weighting described in claim 25 (see 103(a) rejection of claim 25 above).

Schneider as modified by Cho do not address the exact percentages of the weighting of the data. However, the weightings do reflect the most weight being given to the basal temperature data and the least weight being given to the data from the properties of the saliva, which includes the claimed percentages. Applicant has not disclosed that the claimed percentages solve any stated problem. Moreover, it appears

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that the weightings in Schneider as modified by Cho's algorithm, or applicant's invention, would perform equally well for women with regular menstrual cycles and for women with irregular menstrual cycles.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Schneider as modified by Cho such that the percentages of the weightings are 50-90% for basal temperature, 5-35% for the first day of the woman's cycle, and 2-20% for the properties of the saliva, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Schneider as modified by Cho.

8. Claims 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider as modified by Cho as applied to claims ABC above, and further in view of United States Patent 5657762 (Coley et al.).

Regarding claims 28 and 30, Schneider as modified by Cho teach the device according to claims 27 and 29. Schneider as modified by Cho teach that fertile days, infertile days, and transition days are displayed visually in different ways (see 103(a) rejections of claims 27 and 29 above). Schneider as modified by Cho do not teach that the display device shows possible fertile days in red, possible infertile days in green, and transition days in yellow. Coley et al. teach a display device that shows possible fertile days in red, possible infertile days in green, and transition days in yellow (Column 4 lines 32-39, Column 6 lines 20-23, and the bottom of Figure 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such color indicators of fertility as taught by Coley et al. in the invention of Schneider as

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modified by Cho to provide the predictable result of conveying "information on the state of fertility ... by a simple visual indication" (Coley et al. Column 4 lines 34-35).

Response to Arguments

9. Applicant's arguments filed 30 June 2008 have been fully considered but they are not persuasive.

10. Regarding Applicant's arguments that claims 25, 43 and 44 are described in the written disclosure, the Examiner notes that while the disclosure appears to repeat the limitations of the claims, it does not describe how these limitations are performed/applied. For example, it is unclear if each type of data is given a binary value (such as 0 for infertile and 1 for fertile) that is then multiplied with the corresponding percentage to arrive at a total number for all types of data multiplied by their percentages, and if this is the case, what criteria the resulting values are compared to (for example, a total of 0-0.3 indicates infertile, a total of 0.3-0.7 is unsure, and 0.7-1 is fertile). As a further example, it is unclear if each type of data is given a decimal value (such as 0 for infertile and 0.01-0.99 for degrees of fertility) that is then multiplied with the corresponding percentage to arrive at a total number for all types of data multiplied by their percentages, and if this is the case, what criteria the resulting values are compared to (for example, a total of 0-0.3 indicates infertile, a total of 0.3-0.7 is unsure, and 0.7-1 is fertile). As such, the disclosure does not provide a written description of how the claimed weighting actually occurs.

11. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

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combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it was well known in the art that measuring biological fluids could provide data regarding a woman's fertility.

12. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

13. The Examiner additionally notes that Applicant's claimed "means (8) for input of the property of saliva" is a key (line 6 of the first full paragraph of page 16 of Applicant's disclosure) and that Schneider discloses a mucus entry switch 50 (Figure 1). A switch is equivalent to a key for the purpose of entering data, and the portion of the limitation after for indicates the intended use of the means.

14. Regarding Applicant's argument that "the data are weighted differently in determining the conclusion regarding the woman's fertility", the Examiner notes, as examples only, that Schneider Column 20 lines 49-60 states "by weighting today's temperature measurement less" and provides for "simply" filtering and storing the

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temperature under specific conditions. The Examiner also notes that removing or altering data is providing a weight to that data.

15. Regarding Applicant's argument that both devices work independently and therefore there is no reason to combine them, the purpose of a 35 USC 103 rejection is to combine aspects of one invention to another, and in the case of US patents, both devices are always presumed to be operative and functional on their own. A 35 USC 103 rejection is based on what would have been obvious to one having ordinary skill in the art at the time the invention was made; not based on "fixing" one device by modification with another.

16. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
Art Unit 3736

/EML/

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736